Patentability of plants under the EPC – back to square one?

Mike Snodin (Fellow) discusses a wholly predictable ruling from an EPO Board of Appeal, finding rule 28(2) EPC to be in conflict with article 53(b) EPC, as well as the options for resolving tensions between politics and the law that will resurface in the light of the ruling.

On 5 December 2018, EPO Board of Appeal 3.3.04, sitting in enlarged composition[1], issued a decision in case T1063/18[2] which concluded that rule 28(2) EPC conflicts with article 53(b) EPC, as previously interpreted by the EPO Enlarged Board of Appeal (EBA) in cases in G2/12 and G2/13.

It is unusual for a rule of the EPC to be found to be in conflict with an article of the EPC. However, the view of this author is that, in this instance, the conflict was so clear-cut that the Board of Appeal's decision should not come as a surprise to anyone who is familiar with European patent law (and who has faith in the independence of the Boards of Appeal of the EPO). Indeed, the predictability of this outcome is amply illustrated by the fact that the Board of Appeal's conclusion regarding rule 28(2) EPC is entirely in accordance with a view expressed by this author in an article first published in October 2017[3], namely that:

> "there are no valid grounds upon which a Board of Appeal of the EPO could accept the interpretation of article 53(b) EPC as set out in EPC rules 27 and 28 in preference to the Enlarged Board's interpretation as set out in G2/12 and G2/13".

Nevertheless, despite its robust, clear-cut and highly predictable reasoning, the Board of Appeal's decision is certain to provoke controversy. This is not least because the EPO may now struggle to identify a straightforward solution that will dissipate renewed political pressure (from special interest groups, certain EU Member States, the European Parliament and/or the European Commission) to effectively overrule the EPO Boards of Appeal.

Thus, in addition to discussing the decision in T1063/18, this article examines options for resolving tensions between politics and the law that will resurface in the light of that decision. It also discusses factors that might make every one of those options either legally or politically problematic.

Rule 28(2) EPC

Subsequent to an Administrative Council (AC) decision[4] on 29 June 2017, new rule 28(2) EPC entered into force on 1 July 2017, together with a consequential amendment to rule 27. That new rule, which was intended to provide a statutory interpretation of article 53(b) EPC[5] for all patents and patent applications subject to pending proceedings before the EPO, reads as follows:

> "Under article 53(b), European patents shall not be granted in respect of plants or animals exclusively obtained by means of an essentially biological process".

Thus, the intended effect of rule 28(2) EPC was to essentially override the EBA's decision in cases in G2/12 and G2/13, which included the finding that

> "The exclusion of essentially biological processes for the production of plants in article 53(b) EPC does **not** have a negative effect on the allowability of a product claim directed to plants or plant material such as a fruit" (emphasis added).

Does rule 28(2) conflict with article 53(b) ?

The patent application (filed by Syngenta) that was the subject of T1063/18 had been rejected by the Examining Division (ED) on the grounds that subject-matter of the claims fell "within the exception to patentability article 53(b) EPC and rule 28(2) EPC". However, in its appeal, Syngenta asserted that rule 28(2) EPC is in conflict with article 53(b) EPC. The Board of Appeal's first order of business was therefore to decide whether Syngenta's assertion was correct.

When considering this question, the Board of Appeal firstly confirmed that it is bound by the EBA's interpretations of the EPC. Having done this, it concluded that it could not agree with ED's reasoning that rule 28(2) EPC constitutes a "clarification of the scope of article 53(b) EPC" and instead found that:

> "The board, however, cannot deduce from decisions G 2/12 and G 2/13 any other interpretation of article 53(b) EPC than that plants are not excluded from patentability, even if they can only be obtained by an essentially biological process. Since rule 28(2) EPC excludes plants or animals exclusively obtained by means of an essentially biological process from patentability, **its meaning is in conflict with the meaning of article 53(b) EPC as interpreted by the EBA.**" (Emphasis added.)

However, much like the EBA in decisions G 2/12 and G 2/13, the Board of Appeal adopted a methodical approach to the question at hand. Thus, having established that there was a conflict, it went on to consider not only whether there was a way to resolve that conflict (by interpretation of rule 28(2) EPC) but also whether there were any reasons to deviate from the EBA's conclusions in G 2/12 and G 2/13.

In reaching negative conclusions on both points, the Board of Appeal made a number of pertinent observations. Firstly, with regard to the interpretation of rule 28(2) EPC, the Board noted that:

> "Rule 28(2) EPC in fact **reverses** the meaning of article 53(b) EPC, as interpreted by the EBA" (emphasis added).

Secondly, the Board's concluded that there were numerous reasons for *not* deviating from the EBA's interpretation of article 53(b) EPC, including:

> "The interpretation of the Biotech Directive as put forward in the Notice [EU Commission Notice C(2016)6997] **cannot be seen as a relevant development because it has not been confirmed in a legally binding way**. Within the legal framework of the European Union (EU), a binding interpretation of provisions of EU law such as the Biotech Directive are decided in last instance by the CJEU (article 267(b) Treaty on the Functioning of the European Union). This was recognised in the Notice itself (see point 11, above). **The Notice therefore has no legal authority**;
>
> the Administrative Council is **not**, in the light of articles 33(1)(b) and 35(3) EPC, competent to amend the Convention, here article 53(b) EPC, by amendment of the Implementing Regulations, here rule 28(2) EPC;
>
> the decision to adopt rule 28(2) EPC cannot be regarded as a subsequent agreement between the parties that shall be taken into account for the interpretation of the treaty, in the meaning of article 31(3)(a) of the Vienna Convention; and
>
> It goes without saying, that the Notice is not such a subsequent agreement either, as **the Commission does not represent the Contracting States of the EPC.**" (Emphasis added.)

The Board also noted that, in the light of article 164(2) EPC (which stipulates that "In case of conflict between the provisions of this Convention and those of the Implementing Regulations, the provisions of this Convention shall prevail"), a referral to the EBA was not justified.

Finally, in a section addressing submissions that it had received from third parties, the Board commented that:

> "The view that rule 28(2) EPC served to ensure consistency between the Biotech Directive and the EPC and with that legal certainty, is based on the presumption that the Biotech Directive has to be interpreted as set out in the Notice. As explained under point 29 above, **such a presumption is not valid unless the CJEU has decided on the matter, which it has not**. In fact, adopting the interpretation of the Notice in the absence of a decision of the CJEU on the matter, creates a risk of misaligning the provisions of the EPC with the Biotech Directive, should the CJEU later concur with the analysis of the EBA." (Emphasis added.)

Immediate impact of the decision

The Board remitted Syngenta's patent application to the ED. When re-examining Syngenta's application, the ED will be bound by the Board's ruling regarding rule 28(2) EPC. However, it remains to be seen whether they will be persuaded that the application complies with other provisions of the EPC. This is not least because the Board of Appeal expressed the preliminary opinion that the claims in Syngenta's current main request "had deficiencies under articles 84 and 56 EPC".

Thus, although Syngenta succeeded in overcoming a rejection based upon rule 28(2) EPC, it is not yet clear whether they will succeed in securing a patent to the "cultivated blocky fruit type pepper plant" claimed in their current main request.

It is also unclear whether the EPO will either:

a. work with the AC to delete rule 28(2), and return rules 27 and 28 to their previous form; or
b. issue instructions to all relevant EDs to no longer apply rule 28(2) to patent applications claiming "*plants or animals exclusively obtained by means of an essentially biological process*".

As clarified in case J0027/94, the decision of a Board of Appeal is binding "only in the individual case which the board has remitted to the department of first instance". It is therefore theoretically possible for the EPO to continue to apply current rule 28(2) EPC in respect of all other first instance proceedings. Whilst perhaps unlikely (and certainly undesirable from the perspective of consistency and procedural efficiency), such an approach by the EPO might require applicants to appeal negative first instance decisions in order for the Boards of Appeal to reconfirm, on a case-by-case basis, that rule 28(2) EPC indeed conflicts with article 53(b) EPC.

At the time of writing, the EPO had acknowledged that it had been informed of the Board of Appeal's decision[6]. Further, subsequent to a meeting of the Committee on Patent Law on 19 and 20 February 2019, the EPO issued a statement[7] indicating that:

> "The Committee addressed different potential options for the way forward and particularly supported measures to obtain an opinion from the Enlarged Board of Appeal on the matter. The need for legal certainty in the interest of the users of the European patent system and the general public was strongly underlined in the debate. Discussions will continue with the intention to find a solution in the short term".

Nevertheless, it is not yet clear which, if any, concrete actions the AC will take in order to (try to) resolve the situation.

What next?

Amendment of the Implementing Regulations of the EPC requires only a three-quarters majority at a meeting of the AC. The relative ease with which such a majority could be achieved is therefore likely to have been an important factor in the EPO's decision to *try* to overcome G 2/12 and G 2/13 by introducing rule 28(2) EPC.

However, it now appears that the attempt to use rule 28(2) EPC to overturn G 2/12 and G 2/13 has ended in failure. This raises the questions of:

a. whether any further attempts will be made to achieve the same (or a similar) objective; and, if so
b. which approach(es) any such attempts might take?

In the light of the above-mentioned statement from the EPO, as well as the resumption of lobbying by parties (e.g. special interest groups, certain EU Member States, the European Parliament and the European Commission) favouring a different interpretation of article 53(b), it seems likely that the answer to question A above will be "yes".

However, question B is much harder to answer, at least with respect to approaches that stand a reasonable chance of success. This is because each of the remaining options for (trying to) overturn the current interpretation of article 53(b) EPC has its own complications, and none is as straightforward as the (failed) attempt to amend the rules of the EPC. In this respect, the challenges and complications associated with those remaining options are discussed below, together with the alternative option of simply allowing the current interpretation to stand.

Option 1: Amendment of article 53(b) EPC

The view of this author is that, at this time, the AC is *not* competent to amend article 53(b) EPC. This is because article 33(1)(b) EPC only provides the AC with authority to amend Parts II to VIII and X of the EPC in order to:

> "bring them into line with an international treaty relating to patents or European Community legislation relating to patents".

The above-quoted reasoning from T1063/18 makes it abundantly clear that the Commission Notice does *not* in any way represent "European Community legislation". Indeed, this conclusion accords with both:

- the well-established principle that the CJEU has *exclusive* jurisdiction over the definitive interpretation of EU law; and
- settled case law of the CJEU holding that an interpretative notice from the Commission cannot have the effect of modifying the mandatory rules contained in a regulation[8].

Further, the term "European Community legislation" is *not* synonymous with any one or more national laws, even national laws based upon an EU Directive. This is because only the CJEU can provide binding interpretations of EU legislation. Thus, whilst the national laws of France, Germany, Italy and the Netherlands exclude from patentability those plants or animals that are obtained by means of "*an essentially biological process*"), it is still possible that the CJEU will:

- interpret article 4(1)(b) of the Biotech Directive in a manner that does *not* exclude such plants and animals from patentability; and
- effectively force France, Germany, Italy and the Netherlands to either revise or interpret their national laws in ways that permit the patenting of such plants and animals.

Nevertheless, even in the absence of a ruling from the CJEU that interprets article 4(1)(b) of the Biotech Directive, amendment of article 53(b) EPC is still possible. This is because it is open to the AC to convene a Conference of the Contracting States. If such a Conference were convened, article 53(b) EPC could be amended by a majority of three-quarters of the Contracting States represented and voting at the Conference[9].

Thus, provided that at least 29 of the 38 representatives of the Contracting States agree, article 53(b) EPC could be amended to exclude from patentability those plants or animals that are obtained by means of "an essentially biological process".

Option 1: Complications

Whilst amendment of article 53(b) EPC is possible in theory, the view of this author is that it would be extremely unwise for any such amendment to precede a ruling from the CJEU that interprets article 4(1)(b) of the Biotech Directive.

This is because any such amendment would need to be reversed if the CJEU's ruling confirmed the EBA's view (*and* the view of a national court of an EU Member State[10]) that the exclusion from patentability of "essentially biological processes for the production of plants or animals" does *not* extend to the plants or animals obtained by such processes.

Moreover, as discussed in more detail in this author's above-mentioned article from October 2017, complications arise in connection with the obligation of the EU Member States, established by article 267 TFEU[11], to ensure that, any "court or tribunal against whose decisions there is no judicial remedy under national law" **must** seek guidance from the CJEU in circumstances where interpretation of a provision of a relevant EU law is neither:

- *acte éclairé* (i.e. already the subject of a ruling from the CJEU); nor
- *acte clair* (i.e. so obvious that no reasonable doubt is left).

Such complications arise because the Boards of Appeal of the EPO are a relevant court or tribunal but fall outside the institutional and judicial framework of the EU, and so cannot seek guidance from the CJEU by way of a preliminary reference under article 267 TFEU.

Thus, amendment of article 53(b) EPC prior to a CJEU ruling that interprets article 4(1)(b) of the Biotech Directive would give rise to both:

- a grave risk that judgments of Boards of Appeal of the EPO would be issued in contravention of article 267 TFEU (i.e. without guidance having first been sought from the CJEU); and
- a significant risk that the CJEU will ultimately interpret article 4(1)(b) of the Biotech Directive in a manner that is incompatible with article 53(b) EPC as amended.

In other words, amendment of article 53(b) EPC would render the EPC incompatible with EU law in the short term, and possibly also in the long term. Further, and as discussed in more detail in the above-mentioned October 2017 article, AC representatives from EU Member States:

- would, under a principle established in CJEU case law[12], be obliged to block any amendment to article 53(b) EPC that would inevitably lead to Board of Appeal decisions being issued in breach of article 267 TFEU; and
- might, if they ignore that obligation, accrue financial liability (including *personal* financial liability)[13] in respect of each and every instance of a patent applicant or proprietor being denied their right to a preliminary reference under article 267 TFEU.

The question of compatibility of the EPC with EU law, as opposed to human rights law and/or constitutional laws, has so far received scant judicial attention. In this respect, it is difficult to predict precisely how the national courts and the CJEU might handle an allegation of conflict between the two legal systems. Thus, a "premature" amendment of article 53(b) EPC would not only lead to clear breaches of EU law but might also lead to an uncomfortable level of judicial scrutiny in connection with an issue that could represent an Achilles' heel for the EPC, namely of compliance of certain Board of Appeal judgments with article 267 TFEU.

Finally, it is important to note that an amendment to an article of the EPC normally only applies from a specified date. This arrangement protects the legitimate expectations of the proprietors of applications filed prior to the change of legal regime. It is therefore unlikely that an amended version of article 53(b) EPC could legitimately be applied to patents and applications already on file (i.e. applied *retroactively*). For this reason, amendment of article 53(b)

EPC could prove unattractive to those seeking to (directly or indirectly) invalidate existing patent rights.

Option 2: Amendment of the Biotech Directive and the EPC

If the Biotech Directive was amended to exclude from patentability those plants or animals exclusively obtained by means of an essentially biological process, the AC could then rely upon article 33(1)(b) EPC to bring article 53(b) EPC into line with (revised) EU law.

Option 2: Complications

Whilst it is legally viable, Option 2 is not without its own, largely political complications. For example, opening up the Biotech Directive for amendment could lead to other provisions of the Directive being amended in unpredictable ways (and possibly in ways that are extremely damaging to the competitiveness of life science industries in the EU). In view of such risks, at least some EU Member States may have a limited appetite for amending the Biotech Directive.

Moreover, because of the non-retroactive nature of any amendment to the Biotech Directive (and any subsequent amendment to the EPC), Option 2 may well also not be attractive for those seeking to invalidate existing patent rights.

Option 3: Ex officio stay of proceedings

On 24 November 2016, the President of the EPO issued a Notice[14] announcing that:

> "all proceedings before EPO examining and opposition divisions in which the decision depends entirely on the patentability of a plant or animal obtained by an essentially biological process will be stayed *ex officio*".

Whilst the stay of proceedings was eventually lifted, this was only after rule 28(2) EPC came into force. In the light of this precedent, one option that the EPO might explore is another stay of proceedings.

Option 3: Complications

The decidedly questionable basis for the previous stay of proceedings ("*in view of the potential impact of the Commission Notice*") is now clearly out of bounds. This is because the Board of Appeal has ruled that the Commission Notice has no legal authority.

Further, the EBA's rulings in G2/12 and G2/13 mean that the law is already uniformly applied by the Boards of Appeal, and that there is no point of law of fundamental importance that has not already been resolved in connection with article 53(b) EPC.

Thus, any stay of proceedings imposed at this time would not have a relevant legal basis, and could hence be challenged as being *ultra vires*, for example by way of an appeal against the stay, or a claim (in accordance with article 9(2) EPC) against the EPO for non-contractual liability[15].

It is not entirely clear whether application (by an Examining or Opposition Division) of a general stay to a specific case would qualify as an appealable decision in the sense of article 106 EPC. Nevertheless, it is important to note that the question of admissibility would be assessed by a Board of Appeal. Also, recent case law, such as T2377/17 and T2707/16, suggests that at least one Board of Appeal is prepared to view excessively lengthy or slow examination as representing a substantial procedural violation that, at least in some instances, can justify reimbursement of the appeal fee.

Finally, whilst this author is not aware of any precedents for a claim against the EPO for non-contractual liability, the grounds for such an action (namely the imposition of an illegal measure) would be strong. Thus, the main challenge for any such claims would likely relate to demonstrating and/or quantifying losses suffered by the claimant.

Option 4: Obtain another opinion from the EBA

Board of Appeal 3.3.04 concluded that the Commission Notice has no legal authority. Whilst this author is not aware of any reasons to dispute this conclusion, it is perhaps possible (even if somewhat unlikely) that the EBA may reach a different view.

At the February 2019 meeting of the Committee on Patent Law, there was support for "*measures to obtain an opinion*" from the EBA. This would appear to refer to the possibility of asking the EBA to (again) provide their view on how article 53(b) EPC should be interpreted, this time taking account of the Commission Notice.

Option 4: Complications

The view of this author is that, with respect to article 53(b) EPC, there are presently are no grounds upon which the EBA could accept a referral by the President under article 112(1)(b) EPC. This is because the EBA has already provided a binding interpretation of article 53(b) EPC, meaning that there are no "different" (i.e. conflicting) decisions of Boards of Appeal that might form the basis of such a referral.

Also, short of violating the independence of the Boards of Appeal, there would appear to be no plausible way of using the Commission Notice to elicit a "conflicting" decision from a different Board of Appeal. This is because principles established by settled CJEU and EBA case law would appear to make it essentially impossible for any Board of Appeal to accept that a non-contemporaneous interpretative notice from a non-judicial body (the Commission) is capable of overriding prior, judicial interpretations of the EPC.

With regard to EU law principles, and as discussed above in connection with option 1, the CJEU has ruled that

interpretative notices from the Commission cannot have the effect of modifying mandatory rules in EU legislation. Indeed, in the introduction to their Notice, the Commission acknowledges that:

> "The Notice is intended to assist in the application of the Directive, and does not prejudge any future position of the Commission on the matter. **Only the Court of Justice of the European Union is competent to interpret Union law**" (emphasis added).

Thus, as the Commission Notice is not even binding under EU law, it is difficult to see how it could be viewed as persuasive for the interpretation of a provision of a different legal system (i.e. the EPC), let alone as being more persuasive than a prior, judicial interpretation by the EBA.

Further, turning to principles from EBA case law, the ruling in G5/83[16] means that the EPO is obliged to give full consideration to decisions of national courts of the EPC Contracting States. With regard to article 53(b) EPC, this means that the Boards of Appeal would be obliged to give full consideration to a decision of an EPC national court (the Court of Appeal of The Hague in *Cresco v Taste of Nature*) that is in complete alignment with the EBA's current interpretation.

In the light of the above, the view of this author is that, if pursued, Option 4 would not succeed. This is largely because it is impossible to see how any truly independent judicial authority could overturn established, judicial interpretations solely upon the basis of a non-binding view expressed by an executive body many years after the legislation in question first entered into force.

Moreover, even in the unlikely event that Option 4 succeeded in persuading the EBA to revise their interpretation of article 53(b) EPC, the principle of legitimate expectations[17] would almost certainly prevent any revised interpretation from being applied (retroactively) to patents and applications already on file. Thus, as for Options 1 and 2, the non-retroactive nature of the revised interpretation could make Option 4 unattractive to those seeking to invalidate existing patent rights.

Option 5: Accept the current interpretation of article 53(b) EPC

Given that the EBA has already provided a binding interpretation of article 53(b) EPC, a very straightforward option would be for the EPO to simply accept, and work with, that interpretation.

For the EPO, the advantages to adopting such an approach would be numerous. For example, it would avoid all of the complications (including potential liabilities) associated with Options 1 to 4 above. More importantly, however, it would enable:

- the first instance departments of the EPO to devote more time and attention to establishing best practice with regard to the assessment of patentability (under other provisions of the EPC) for plants and animals produced by essentially biological processes; and

Notes and references

1. Comprising the five members specified in article 21(3)(b) EPC instead of the more usual three members
2. An appeal against the rejection of EP application no. 12756468.0 (filed by Syngenta and directed towards "New pepper plants and fruits with improved nutritional value")
3. Snodin, M. "Patentability of plants under the EPC: act in haste, repent at leisure?", *Bio-science Law Review*, Vol. 16, Issue 3 (October 2017), also published as Snodin, M. "Patentability of plants under the EPC", December [2017] *CIPA* 11
4. Decision no. CA/D 3/17 (OJ EPO 2017, A55)
5. Article 53(b) provides: "European patents shall not be granted in respect of: … (b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof."
6. See *https://bit.ly/2UZOqpl*
7. EPO news update from 20 February 2019 (see *https://bit.ly/2Xb9dZf*)
8. See, for example, C−266/90 (*Soba*), paragraph 19 and T−81/12 (*Beco Metallteile-Handels GmbH*), paragraph 50
9. See article 172(2) EPC
10. *Cresco v Taste of Nature*, the Court of Appeal of The Hague, 28 May 2013 (*http://bit.ly/2rH5S80*)
11. As interpreted, for example, by C-283/81 (*Cilfit*; *http://bit.ly/2h2Awnz*)
12. See, for example, C-124/95 (*Centro-Com*; *http://bit.ly/2v88Eo2*)
13. In accordance with principles established by the CJEU, e.g. in C-46/93 / C-48/93 (*Brasserie du Pêcheur / Factortame*; *http://bit.ly/2tM14iB*) or C-470/03 (*A.G.M.-COS.MET*; *http://bit.ly/2h58F6f*).
14. OJ EPO 2016, A104
15. These possibilities are discussed in 14 January 2017 and 11 February 2019 blog posts by Christopher Rennie-Smith (see *https://bit.ly/2TOcQC6 and https://bit.ly/2tiPtVL*).
16. See paragraph 6 of the Reasons for the Decision in G5/83 (OJ EPO 1985, 64; *http://bit.ly/2w1lcuz*)
17. See, for example, J25/95 (*http://bit.ly/2w3KCqR*) and the discussion at III.A.5 of *Case Law of the Boards of Appeal of the EPO* (*http://bit.ly/2v34MUA*)
18. T1957/14, an appeal against the rejection of EP application no. 08701583.0 (filed by Syngenta and directed towards "Maize plants characterised by quantitative trait loci (QTL)")

- the Boards of Appeal to continue to develop relevant case law in connection with the patentability of such plants and animals.

In this respect, it is noteworthy that, prior to its decision in T1063/18, EPO Board of Appeal 3.3.04 issued a decision[18] in which claims to a maize plant defined by reference to certain QTLs (*quantitative trait loci*) were held to lack clarity. This decision is important because QTLs, which are essentially "markers" in the DNA of a plant that correlate with a particular trait, are often used to define plants produced by essentially biological processes. Further, whilst a lack of clarity was found because of the manner in which the QTLs in question were defined, views expressed by Board 3.3.04 (including the necessity for the claims to "convey to the skilled person the structural features necessary to unambiguously characterise the alleles referred to in the claim") suggest that clarity may now present a significant hurdle for those seeking to patent plants produced by conventional breeding techniques.

Option 5: Complications

As for Option 2, the complications for Option 5 are political in nature. That is, given the strength of views expressed by those seeking to effectively overturn the EBA's interpretation of article 53(b) EPC, it is perhaps unlikely that cool heads will prevail for long enough for the case law and practice of the EPO to evolve to the point where practically no patents of questionable validity are granted in respect of plants produced by conventional breeding techniques.

Further, even if EPO case law and practice were given sufficient time to evolve, it is doubtful that this would eliminate calls for further action. This is because at least some of the parties whose lobbying prompted the introduction of rule 28(2) EPC appear to have the objective of eliminating all patents to plants produced by conventional breeding, *including* patents that are unquestionably valid under the current (interpretation of the) EPC.

Summary and conclusions

In the light of the above, it is clear that there would be significant legal peril for the EPO if it were to make any further attempts to (retroactively) overturn the EBA's interpretation of article 53(b) EPC, or to impose a further stay of proceedings in respect of patents and applications whose validity rests upon that interpretation. This conclusion is unsurprising, as any such attempts would represent a clear breach of:

- the principle of separation of powers, wherein the judiciary alone is responsible for interpreting existing legislation;
- the principle of protection of legitimate expectations (e.g. the legitimate expectation that an amended version of article 53(b) EPC will not be applied *retroactively* to cases filed before the amendment was made); and/or
- the right afforded to patentees / applicants by article 267 TFEU to seek clarification from the CJEU on the interpretation of a relevant provision of EU law (in this case, article 4(1)(b) of the Biotech Directive) that is neither *acte éclairé* nor *acte clair*.

By way of comparison, the other options open to the EPO (Options 2 and 5 above) would be legally viable yet hardly uncontroversial.

The EPO has signalled its intention to "*find a solution in the short term*". However, with the exception of the (politically) rather controversial Option 5 above, it is not apparent how any short-term solution would also satisfy the EPO's objective of providing "legal certainty in the interest of the users of the European patent system and the general public".

It is therefore fair to say that the EPO is currently standing at a crossroads, and must now decide whether to obey the rule of law or to bow to political pressure. Whilst hardly being reassured by the EPO's immediate reaction to the Board of Appeal's ruling, and despite having been disappointed by political pressure prevailing in 2017, this author earnestly hopes for a different outcome in 2019.

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